

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today
(1) was not written for publication in a law journal and
(2) is not binding precedent of the Board.

Paper No. 21

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JACOB STOLTZE
and JORGEN KAMSTRUP-LARSEN

Appeal No. 1998-3366
Application No. 08/591,506

HEARD: MAY 3, 2000

Before McCANDLISH, *Senior Administrative Patent Judge*, STAAB
and GONZALES, *Administrative Patent Judges*.

STAAB, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on an appeal from the examiner's
final rejection of claims 1-4 and 7-14. Claims 5 and 6, the
only other claims pending in the application, have been
indicated as being allowable if rewritten in independent form.

Appeal No. 1998-3366
Application No. 08/591,506

An amendment filed

Appeal No. 1998-3366
Application No. 08/591,506

subsequent to the final rejection on October 23, 1997 has been entered. See the advisory letter mailed November 17, 1997.

Appellants' invention pertains to a catheter system for introducing and implanting a stent into a tubular vessel within the body. The system includes a catheter member having an inflatable portion and an expandable stent, capable of permanent deformation when expanded, releasably attached to the inflatable member by a bond. Claim 1, the sole independent claim on appeal, is representative of the appealed subject matter and reads as follows:

1. A catheter system for introducing and implanting a stent member in a body comprising:

a catheter member having first and second ends, said first end having an inflatable portion, a lumen in fluid communication with said inflatable portion and said second end to provide means for inflating said inflatable portion; and

an expandable stent member capable of permanent deformation when expanded, at least a portion of said stent member being releasably attached to said inflatable portion by a bond, said bond being capable of adhesively connecting said stent member to said inflatable portion with an adhesive force which is less powerful than a shear force applied by the inflatable portion upon inflation of said inflatable portion such that said bond is capable of separating from said stent member and remaining with said inflatable portion upon release of said stent member from said inflatable portion upon inflation of said inflatable portion to permit deployment of said stent member and removal of said catheter member.

Appeal No. 1998-3366
Application No. 08/591,506

Appeal No. 1998-3366
Application No. 08/591,506

The references of record relied upon by the examiner in support of the rejections are:

Burton et al. (Burton) 1991	5,026,377	Jun. 25,
Lee 1994	5,292,321	Mar. 8,
Forman et al. (Forman) 1996	5,505,699	Apr. 9,
Lau et al. (Lau) 1997	5,603,721	Feb. 18,
		(filed Nov. 13, 1995)

The following rejections under 35 U.S.C. § 103 are before us for review:

a) claims 1-4, 7, 13 and 14, unpatentable over Lau in view of Burton;

b) claims 8 and 9, unpatentable over Lau in view of Burton and further in view of Forman; and

c) claims 10-12, unpatentable over Lau in view of Burton and Forman, and further in view of Lee.

The rejections are explained in the examiner's answer (Paper No. 14, mailed April 28, 1998).

The opposing viewpoints of appellants are set forth in the main brief (Paper No. 13, filed January 22, 1998) and the reply brief (Paper No. 15, filed June 22, 1998).

Considering first the § 103 rejection of claim 1, this claim calls for a catheter system that includes an expandable stent capable of permanent deformation when expanded releasably attached to the inflatable portion of a catheter by a bond having certain capabilities, including the capability "of separating from said stent member and remaining with said inflatable portion . . . upon inflation of said inflatable portion to permit deployment of said stent member" (claim 1, emphasis added).

Lau, the examiner's primary reference, pertains to a catheter system comprising a catheter member 11 having an inflatable portion 14 and an expandable stent 10, capable of permanent deformation when expanded, attached to the inflatable member. Lau describes the attachment of the stent to the inflatable portion of the catheter as follows:

A variety of means for securing the stent to the expandable member on the catheter for delivery to the desired location are available. It is presently preferred to compress the stent onto the balloon. Other means to secure the stent to the balloon include providing ridges or collars on the inflatable member to restrain lateral movement, or using bioresorbable temporary adhesives. [Column 2, lines 18-25.]

Burton, the examiner's secondary reference, is directed to an instrument for the deployment of a self-expanding stent in a body canal. Burton's catheter comprises an outer sleeve 1 having a hollow core 5 axially disposed therein, and a braided, self-expanding stent 10 disposed between the outer sleeve and the hollow core. The stent 10 is constrained to a contracted position by the outer sleeve 1 (column 6, lines 17-23). The stent is deployed by withdrawing the outer sleeve 1 backward toward the handle of the core 5, thus exposing the stent 10, which, free from the constraint of the outer sleeve, expands to its expanded state (column 6, lines 37-47). Provided around the periphery of the core at its distal end is a grip member 9 that releasably grips the stent to prevent it from moving axially relative to core during deployment (see Figure 3). Alternatively, a grip member 9A in the form of a coating of adhesive (see Figure 4) may be employed. The grip member may also take the form of a core 5 made of high friction material having an enlarged end portion 9B (see Figure 5).

In rejecting claim 1, the examiner considers that Lau discloses a catheter system generally as claimed including a

Appeal No. 1998-3366
Application No. 08/591,506

bond formed by bioresorbable temporary adhesive between the stent and the inflatable portion of the catheter. The examiner concedes that Lau does not teach a bond between the stent and the inflatable portion that is capable of separating from said stent and remaining with the inflatable portion upon release of the stent from the inflatable portion. The examiner further considers that Burton discloses in Figure 4 a stent delivery system having an adhesive grip member 9A that stays on

Appeal No. 1998-3366
Application No. 08/591,506

the core after the stent is released. Based on these teachings,
the examiner concludes that it would have been obvious to one of ordinary skill in the art:

to modify Lau's temporary adhesive on the balloon with the adhesive grip member as taught by Burton so as to remain on the stent mounting portion upon release of the stent from the stent mounting portion. In addition, whether choosing a temporary or a permanent adhesive is considered as a matter of design choice since it appears that the bioresorbable temporary adhesive would perform equally well with the permanent adhesive on the balloon for securing the stent on the balloon of the catheter. [Answer, pages 4-5.]

Implicit in the above is the examiner's position that the above modified catheter system of Lau would correspond in all respects to the subject matter of claim 1.

We will not sustain this rejection.

Our first difficulty with the examiner's rejection concerns the failure of the references to suggest, either individually or collectively, a reason for the proposed modification. In this regard, the examiner's rationale that the proposed modification of Lau would have been obvious "as a matter of design choice" and/or because each of the bioresorbable temporary adhesive of Lau and the so-called

"permanent adhesive" of Burton "would perform equally well" is not sufficient.

Furthermore, the disparate ways in which the stents of Lau and Burton are deployed cannot be ignored in considering the question of obviousness presented in this appeal. As is clear from a reading of Burton, the function of the adhesive 9A is to prevent the stent 10 from moving axially relative to the core 5. Thus, Burton's adhesive 9A is akin to a friction enhancing element. When the outer sleeve 1 of Burton is withdrawn backward toward the handle of the core, the stent's ability to self-expand is sufficient by itself to break the bond of adhesive 9A. In Lau, the temporary bioresorbable adhesive referred to at column 2, lines 24-25, intimately bonds the stent and the inflatable portion of the catheter together to form a catheter-stent assembly that remains intact until the bond is ruptured by forces resulting from inflation of the inflatable portion of the catheter. Given these differences in operation, we consider the proposed modification of Lau in view Burton to be a hindsight reconstruction based on appellants' teachings rather than on anything that is fairly taught by the references themselves.

Finally, it is debatable whether the proposed modification of Lau in view of Burton would result in the claimed catheter system, namely, a catheter system wherein the stent is bonded to an inflatable portion of a catheter by a bond that is capable of remaining with the catheter when the inflatable portion of the catheter is inflated to deploy the stent. The circumstance that Burton's adhesive is "releasable" does not necessarily mean that it remains with the catheter when the stent is deployed.

For these reasons, we cannot sustain the standing § 103 rejection of claim 1, or claims 2-4, 7, 13 and 14 that depend therefrom, as being unpatentable over Lau in view of Burton.

We also have carefully reviewed the Forman reference additionally relied upon by the examiner in rejecting claims 8 and 9, and the Lee reference additionally relied upon by the examiner with Forman in rejecting claims 10-12, but find nothing therein that makes up for the deficiencies of Lau and Burton discussed *supra*. Therefore, we also cannot sustain the standing § 103 rejections of these dependent claims.

Appeal No. 1998-3366
Application No. 08/591,506

The decision of the examiner is reversed.

REVERSED

)	
HARRISON E. McCANDLISH)	
Senior Administrative Patent Judge)	
)	
)	
)	BOARD OF PATENT
LAWRENCE J. STAAB)	
Administrative Patent Judge)	APPEALS AND
)	
)	INTERFERENCES
)	
JOHN F. GONZALES))
Administrative Patent Judge)	

LJS:hh

Appeal No. 1998-3366
Application No. 08/591,506

DANIEL A. SCOLA, JR.
HOFFMANN & BARON
6900 JERICO TURNPIKE
SYOSSET, NY 11791